

PSJ3
Exhibit 173

Message

From: Will Rowe [wrowe@painfoundation.org]
Sent: 12/10/2008 9:42:35 AM
To: Lunner, Kristina [KLunner@APHANET.ORG]
CC: Rosen, Burt [/O=PURDUE/OU=PURDUE US/CN=RECIPIENTS/CN=ROSENBU]; mbough@aphanet.org; pvanpelt@aphanet.org; Hagel, Harry [HHagel@APHANET.ORG]
Subject: RE: PCF REMS Task Force

Hello Kristina,

Thanks for your comments. I'm hoping that, with your input, we will develop a letter that accomplishes the goal of the FDA accepting the invitation to discuss REMS design with stakeholders. Several comments were offered during our last call and several more have been submitted by mail, that reflect some concerns similar to yours. We hope to develop a letter that is amenable to all the principal stakeholders who would eventually be involved in meeting with the FDA to develop the best possible REMS design.

Hope to see you at our December 11th meeting.

Regards,

Will

From: Lunner, Kristina [mailto:KLunner@APHANET.ORG]
Sent: Tuesday, December 09, 2008 6:18 PM
To: Will Rowe
Cc: Bough, Marcie; Hagel, Harry; VanPelt, Peter; Rosen, Burt
Subject: FW: PCF REMS Task Force

Will,
Thank you for providing APhA the opportunity to comment on the attached letter. Instead of providing specific edits, I will share some general thoughts. At this time, APhA is unable to co-sign a letter as specific as the one that is attached. While we fully support the need to make REMS as least burdensome as possible, thereby better ensuring patient access to needed medications, we have not come to any conclusion as to how to reach that goal.

At this time, we are not prepared to support a class-wide REMS that could incorporate all drugs in a class. Our understanding of the proposed class-wide REMS is that all drugs in a class would be subject to a REMS regardless of any particular drug's risk profile. Please correct me if we misunderstand the proposal. Furthermore, we are not prepared to comment on the specific elements of a standardized REMS, for example whether prescriber and pharmacist "certification" should be required.

Because we strongly support the goals of this task force, APhA would like to continue to participate in it. We believe the task force's dialogue will help inform us as we continue to develop our internal policy.

Best regards,
Kristina

Kristina Lunner, Vice President
Government Affairs

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APhA was established in 1852 as the American Pharmaceutical Association.

From: Will Rowe [<mailto:wrowe@painfoundation.org>]

Sent: Wednesday, December 03, 2008 5:21 PM

To: Bough, Marcie; gwt@u.washington.edu; Aaron Gilson, PhD; Adam Chrisney; Adam Michael Clark, PhD; Amanda Seeff-Charny; Barry Eliot Cole; Brad Gary; Brad Maruca; Brian Munroe; Burt Rosen; Carlos Gomez, MD, PhD; Caroline Moody; Christy Torkildson; Claudia Campbell, RN, BSN; Courtney Snowden; Dan Cohen; David Joranson; David Swankin; David Woodmansee; Gail Katz; Janet McUlsky; Jason Grove; Jeff Myers; Jennifer M. Connelly; Jerold Roschwalb; Jim Broatch; Joel Kurzman; Jonathan Keyserling; Joy Buck, RN, PhD; Joy Buck, RN, PhD; June Dahl; Karina Tabor; Kathryn Tucker; Kimberley Tiller; Lunner, Kristina; Lennie Duensing; Linda Wase; Lisa Robin; Mark Rasmussen; Mark W. Caverly; Marsha Stanton, MS, RN; Mary Bennett; Mary Patt aardrup; Michael Splaine; Michelle Lonchar; Micke Brown; Mike Matoon; Myra Christopher; Nancy Buermeyer; Ned Masin, M.D.; Pamela Bennett; Patricia Barnett; Paul Arnstein, MD; Penney Cowan; Peter Slone; Rebecca Kirch; Robert J. Saner; Robert Twillman, PhD; Scott Fishman, MD; Scott Melville; Stephen Porada; Steve LaPierre; Susan Rogers, MS, BSN, RN, CHPN; Tamara Sloan Anderson; Tamara Sloan Anderson; Theresa Doyle; Tom Berry

Subject: PCF REMS Task Force

Dear All:

Thank you to all who participated in our 12/1 call regarding the REMS. We collected some valuable comments to include in a revised letter to the FDA. As I mentioned at the phone meeting, our strategy is to request a meeting with the FDA to express our understanding and concerns about the REMS and offer our ideas about how an opioid-class REMS might be constructed to minimize risks and protect access to opioid medicines for people who could benefit from them.

Attached is the draft I sent out before our last meeting. We would appreciate your thoughts/edits in writing so that we may construct a second draft that best reflects our collective concerns and ideas. Please send your thoughts/edits to me, wrowe@painfoundation.org, by Tuesday 12/9. We are planning a working group on 12/11 to redraft the letter which we will recirculate before our next meeting (which will be announced shortly). We would like to send the letter shortly after the 1st of the year.

Thank you.

Will

Will Rowe
Chief Executive Officer

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